

### REMARKS

Applicant requests reconsideration of the application in view of the foregoing amendments and the discussion that follows. The status of the claims as of this response is as follows: Claims 1-6, 13-25, 27, 30 and 31 are pending. Claims 7-12, 26, 28, 29 and 32 were previously canceled. Claims 25, 27, 30 and 31 have been amended herein.

#### The Amendments

Claim 25 was amended to eliminate the double usage of "Z'."

#### Claim Objections

Claims 25, 27, 30 and 31 were objected to because of informalities, which, Applicant believes are obviated by the amendments to those claims.

#### Rejection under 35 U.S.C. 102

Claims 1-5 were rejected again under paragraph (e) of the above code section as being anticipated by Pouletty, *et al.* (U.S. Patent Publication 2003/0171435 A1) (Pouletty) for reasons set forth in the previous office action.

Applicant submits that Pouletty does not anticipate the present claims. The reference does not disclose or suggest the compounds and methods as claimed wherein the linking group is  $-O(CH_2)_nC(O)-$  to an immunogen or a label.

The Office Action indicates that the above assertion was not convincing and asserted that Pouletty discloses compounds (e.g., formulas I, II, IIIa, IV etc.) for coupling to appropriate carriers to render the amphetamine derivatives immunogenic. The Office Action refers to paragraph [0011] and claims 16, 17 and 20 of Pouletty.

The compounds of formula I are directed to compounds that, when coupled to a carrier and administered to an animal, produce antibodies directed against amphetamine derivatives. Nothing is revealed concerning the actual coupled compounds; only the compounds to be coupled are disclosed. In paragraph [0016], one of the designated embodiments for  $R_5$  is  $-O-(CH_2)_m-R_{10}$  wherein  $R_{10}$  may be carboxyl. However, there is no teaching regarding coupling this compound to a carrier. Claim 16, which does disclose compounds linked to a

carrier, does not disclose or suggest linking from the 4-position of the benzene ring and further does not show a  $-\text{O}-(\text{CH}_2)_m-\text{C}(\text{O})-$  as a linking group. While there is a disclosure of  $\text{R}_5$  at the 4-position where  $\text{R}_5$  may be  $-\text{O}-(\text{CH}_2)_m-\text{R}_{10}$  wherein  $\text{R}_{10}$  may be carboxyl, this disclosure teaches nothing more than the aforementioned paragraph [0016].

With regard to claim 17 of the reference, which does show linking through the 4-position of the benzene ring, no carboxylic acid functionality is shown. As can be seen from the language of the claim,  $\text{R}_{11}$  may be  $-\text{O}-(\text{CH}_2)_m-$ ; however, the reference does not show a  $-\text{O}-(\text{CH}_2)_m-\text{C}(\text{O})-$  as a linking group.

Claim 20 is similar to claim 16 in that it does not show linking at the 4-position of the benzene ring and further does not show a  $-\text{O}-(\text{CH}_2)_m-\text{C}(\text{O})-$  as a linking group from the nitrogen of the amine side chain.

It is also apparent from the reading, argues the Office Action, that carriers can be linked through amine nitrogen, referring to paragraph [0064] of the reference. However, the paragraph in question does not show linking at the 4-position of the benzene ring and further does not show a  $-\text{O}-(\text{CH}_2)_m-\text{C}(\text{O})-$  as a linking group.

The Office Action refers to paragraphs [0066] and [0068] of Pouletty for linking through the 4-position of the benzene ring. This disclosure is similar or identical with that of claim 17 of the reference, which does show linking through the 4-position of the benzene ring, but does not show a carboxylic acid functionality is shown. As can be seen from the language in the accompanying paragraphs,  $\text{R}_{11}$  may be  $-\text{O}-(\text{CH}_2)_m-$ . The reference does not show a  $-\text{O}-(\text{CH}_2)_m-\text{C}(\text{O})-$  as a linking group.

The Office Action asserts that the linker  $-\text{O}(\text{CH}_2)_n\text{C}(\text{O})\text{OH}$  is disclosed in several places in the reference (e.g., paragraphs [0011-0016] in which  $\text{R}_5$  of formula (I) is  $-\text{O}(\text{CH}_2)_n\text{C}(\text{O})\text{OH}$  wherein  $\text{R}_{10}$  is carboxyl and in formula (IIa), the linker at position 4 of benzene ring is  $-\text{O}(\text{CH}_2)_n\text{C}(\text{O})\text{OH}$ . Also, argues the Office Action, the compound of formula (IV) of paragraph [0027] of Pouletty discloses the linker  $-\text{OCH}_2\text{C}(\text{O})\text{OH}$ . When this linker is linked to amino group of a protein or peptide, contends the Office Action, it would form an amide bond by eliminating the hydroxyl group, leaving the linker portion  $-\text{O}(\text{CH}_2)_n\text{C}(\text{O})-$  (i.e.  $-\text{O}(\text{CH}_2)_n\text{C}(\text{O})\text{peptide}$ ) (see paragraph [0063]) and, therefore, concludes

the Office Action, the linkers disclosed in this reference correspond to the linker  $-\text{O}(\text{CH}_2)_n\text{C}(\text{O})-$  of present application.

Applicant respectfully traverses the above argument. The group  $-\text{O}(\text{CH}_2)_n\text{C}(\text{O})\text{OH}$  is not disclosed as a linker. As a matter of fact, in every instance in Pouletty where linking at the 4-position of the benzene ring is disclosed, the linker does not include the carboxyl functionality. As discussed above,  $\text{R}_{11}$  may be  $-\text{O}(\text{CH}_2)_m-$  as a linker from the 4-position in the carrier compounds of Pouletty. The reference does not show a  $-\text{O}(\text{CH}_2)_m\text{C}(\text{O})-$  as a linking group.

### Rejection under 35 U.S.C. 103

Claims 6, 13-25, 27 and 30-31 were rejected again under 35 U.S.C. 103(a) as unpatentable over Hui, *et al.* (EP 1,340,981 A2) (Hui) in view of Pouletty for the reasons of record.

Without acquiescing in the rejection of the aforementioned claims, Applicant submits that Claims 6, 13-25, 27 and 30-31 are patentable over Hui in view of Pouletty. The combined teachings of the references do not disclose or suggest the compounds of the present claims. Hui does not disclose or suggest the compounds and methods as claimed wherein the linking group is  $-\text{O}(\text{CH}_2)_n\text{C}(\text{O})-$  to an immunogen or a label. As discussed above, Pouletty is also deficient with regard to such a disclosure. Accordingly, the combination of Hui and Pouletty does not result in the presently claimed compounds and methods.

It may be argued that Pouletty actually teaches away from a linking group as presently claimed. When Pouletty shows a carboxylic acid linked to an amine of a carrier, the linking group does not include  $-\text{O}(\text{CH}_2)_m-$  attached to the carboxylic functionality or otherwise. When the reference discloses linking from the 4-position of the benzene ring, the linking group does not include a carboxylic acid functionality. In the latter instance, only a polymethylene chain or an oxy-polymethylene chain is disclosed.

Claims 6, 13-25, 27 and 30-31 were rejected again under 35 U.S.C. 103(a) as unpatentable over Rouhani, *et al.* (GB 2361473 A) (Rouhani) in view of Pouletty for reasons presented in the previous office action. For reasons similar to

those discussed above with regard to the rejection of the above claims over Hui in view of Pouletty, Claims 6, 13-25, 27 and 30-31 are not disclosed or suggested by a combination of the teachings of Rouhani and Pouletty.

Conclusion

Applicant has demonstrated that Claims 1-6, 13-25, 27, 30 and 31 satisfy the requirements of 35 U.S.C. 102 and 103. Claims 25, 27, 30 and 31 were amended to address the informalities set forth in the Office Action. Allowance of the above-identified patent application, it is submitted, is in order.

Respectfully submitted,

A handwritten signature in cursive script, reading "Theodore J. Leitereg".

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